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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,602	09/05/2000	Anders Carlsson	13454NP	4856

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EXAMINER	
GOLLAMUDI, SHARMILA S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,602	CARLSSON ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

Receipt Remarks and Amendments received on February 6, 2004 is acknowledged.

Claims **1-13** are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The rejection of claims 1-7, 9-11, and 13 under 35 U.S.C. 102(e) as being anticipated by Carlsson et al (6,068,860) is maintained.

Carlsson et al disclose a pharmaceutical formulation containing a glucocorticoid, foscarnet, and galactolipids (example 5). The composition provides an anti-inflammatory agent to the skin. See column 4, lines 15-17. The galactolipids are from oats (example 5). The galactolipid material further contains 70-80% digalactosyldiaacylglycerol and 20-30% of other polar lipids. See column 5. The reference teaches the actives dissolved or encapsulated in a liposome containing galactolipids, which penetrates the skin rapidly provides an improved accumulation of foscarnet in the living epidermis, it can sustain a

high concentration of the active, and is chemically and physically stable (col. 4, lines 10-25 and col. 10, line 35 to col. 11, lines 60). Further, glycerol is taught. See examples.

Response to Arguments

Applicant argues the terminology "prolonged" and argues that the examiner has applied hindsight. Applicant argues that Carlsson et al teach concentrating an active substance and preparing a composition that rapidly penetrates the skin to target a specific site whereas instant invention allows for the prolonged effect of the active. Applicant argues that the examiner has not rejected the claims under 35 U.S.C.112, second paragraph for being indefinite but argues the merits of indefiniteness.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, it is pointed out that the applicant bases his arguments on the preamble, i.e. "a method of prolonging". However, a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In instant case, the methodology steps of the claims are examined since they do not depend on the preamble for completeness. Carlsson et al disclose oil-in-water emulsions containing an active agent and instant amount of galactolipid, which is applied topically. Thus, the prior art anticipates all the instant methodology steps a thorough d. Applicant has not provided any structural limitations different than the prior art's to provide applicant's composition

to provide for a "prolonged" effect compared to the prior art. Therefore, since the instant claims and the prior art's method steps are the same, it is the examiner's position that the prior art inherently performs applicant's preamble.

Secondly, the applicant has misconstrued the examiner's arguments in the last office action, the examiner did not contend nor did the examiner state that the claims are indefinite. The examiner pointed out that a specific parameter, i.e. a specific time period, was not recited in the claims. Therefore, the term "prolonged" is given its broadest reasonable interpretation. It is noted that the definition of prolong and accumulate are different. However, the examiner again points out that the duration of a drug's effectiveness is inherently increased since this accumulation allows for a continued dose at the site, which is in essence is prolonging the effective action of the drug since more drug molecules are available to provide for a longer effect. Further, Carlsson clearly states on column 4, lines 11-15 that the composition can "**sustain** a high concentration of foscarnet in the living epidermis." The examiner points out that the Webster's definition of "sustain" is to "keep up or prolong". The mere change in terminology does not extend patentability when the subject matter of the claims is not distinguishable over the prior art.

Therefore, the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Rejection of claims 1-9 and 12-13 under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (5,688,528) in view of Brodin et al (5,912,271) is maintained.

Carlsson et al teach an oil-in-water emulsion containing galactolipid material as an emulsifier in the amount of 0.1-10% and active agents. The composition may be formulated for topical administration. See column 4, line 35. The galactolipid material consists of about 70-80% digalactosyldiacylgylcerol and 20-30% of other polar lipids. See column 2, lines 42-45. The galactolipid material is prepared from oat kernels. See examples. The composition may contain other conventional excipients such as thickening agents, preservatives, antioxidants, etc. See column 3, lines 48-52 and examples. The preservatives, thickeners, and oils are taught in the instant amounts. See examples. The inclusion of dermatological agents and linoleic acids are taught in column 3, lines 28-67 Glycerol is taught in example 18 with an anesthetic drug. Lastly, Carlsson teach the galactolipid material affords stability to the formulations.

Carlsson et al do not specify the function of the galactolipid.

Brodin et al teach a topical pharmaceutical preparation for anesthetic agents. The composition contains the active agent in the amount of 1-40%, a polar lipid (galactolipid) in the amount of 1-10%, triglycerol in the amount of 50-85%, and water. See column 2, lines 11-25. Brodin teaches that the polar lipids, sphingolipids or galactolipids have a dual function of reducing the onset time and extent the duration of the active agent and acting as a dispersing agent and stabilizer in the formulation.

Brodin results indicate the polar lipids function of prolonging the effect of the active agent. See column 5.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Carlsson et al and Brodin et al and expect the galactolipid formulation of Carlsson's to have a prolonged effect. One would have be motivated to do so since Brodin teaches the functional property of galactolipid to prolong the effectiveness of the active agent. Therefore, although Carlsson does not explicitly disclose this functional property of the galactolipid in the formulation, one would expect this property in Carlsson's formulation since "prolonged effectiveness" is known in the art at the time the invention was made.

Response to Arguments

Applicant's arguments pertain to US patent 6,068,860 to Carlsson et al and the merits of the obviousness rejection are not addressed.

The merits of Carlsson et al have been addressed above and thus the rejection is maintained. The examiner again points out that the secondary reference clearly teaches the role of the galactolipid in prolonging the effect of the active agent.

Rejection of claims 10-11 under 35 U.S.C. 103(a) as being unpatentable over Carlsson et al (5,688,528) in view of Brodin et al (5,912,271), in further view of Cooper et al (4,552,872) is maintained.

AS set forth above, Carlsson et al teach an oil-in-water emulsion containing galactolipid material as an emulsifier in the amount of 0.1-10% and active agents such as dermatological agents. Brodin et al teach the functional property of galactolipids.

The references do not teach the inclusion of a corticosteroid.

Cooper et al teach a topical composition containing corticosteroid for inflammatory conditions such as atopic dermatitis. See abstract and column 12, lines 13.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the references and utilize corticosteroid for the treatment of dermatitis. One would be motivated to do so since Cooper teaches the use of corticosteroids for the treatment of inflammatory conditions such as dermatitis.

Response to Arguments

Applicant's arguments pertain to US patent 6,068,860 to Carlsson et al and the merits of the obviousness rejection are not addressed.

The merits of Carlsson et al have been addressed above and thus the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-242-0614. The examiner can normally be reached on M-F (8:00-5:00) with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

April 20, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER